



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of:

Applicant(s): Dieter Grob et al.

Serial No: 10/762,008

Filing Date: January 21, 2004

Title: CERVICAL FACET RESURFACING IMPLANT

Examiner: Mary C. Hoffman

Art Unit: 3733

Docket No. HORA.P0102US

**DECLARATION OF JOHN E. SHERMAN, M.D.
Pursuant to 37 C.F.R. § 1.132**

I, John E. Sherman, declare as follows:

1. I am an orthopaedic surgeon for Twin City Orthopedics-Orthopaedic Consultants Division, where I have been since 2002. My primary area of emphasis is spinal surgery.

2. I received a B.A. in Chemistry from St. Olaf College in 1978 and an M.D. from Washington University School of Medicine in 1982. I performed a general surgery residency at the University of Minnesota Department of General Surgery from 1982 to 1983 and an orthopaedic surgery residency at the University of Minnesota Department of Orthopedic Surgery from 1983 through 1987. Following my orthopaedic surgery residency, I performed a fellowship at the University of California, Los Angeles Department of Orthopedics from 1989 to 1990, where I served as an assistant professor of surgery-spine. Since 1995, I have been serving as an assistant clinical instructor at the University of Minnesota Department of Orthopedics.

3. I have received several awards for my work in the area of spine surgery. I received the Volvo Award from the International Society and Study of Lumbar Spine for Cauda Equina Compression, the 1991 Acromed Award from the North American Spine Society, the 1992 Young Investigator Award from the Orthopedic Research Society and the 1993 Acromed Award from the North American Spine Society Research Award, Spinal Cord Injury.

4. I have reviewed the published US Patent Application 2005/0159746 ("the Grob application") and the currently pending claims associated with that application. I have also reviewed US Patent No. 6,113,637 to Gill, US Patent No. 6,132,464 to Martin

and US Patent No. 5,571,191 to Fitz, each of which the United States Patent Office cited in its current examination of the Grob application.

5. As I understand the Grob application, the cervical facet implant of the Grob application provides new articulating surfaces for the facets of adjacent cervical vertebrae. The cervical facet implant of the Grob application includes at least a superior implant and an inferior implant. The superior implant is placed on a superior articular facet of a cervical vertebra and the inferior implant is placed on an inferior articular facet of an adjacent cervical vertebra. After placement, the superior implant and inferior implant interact with one another so as to provide new articulating surfaces for the articular facets upon which they are placed.

6. Due to the design of the facet implant of the Grob application, both the superior implant and the inferior implant are capable of being placed on respective cervical articular facets without resecting the facet. As such, the Grob implant is most accurately described as a cervical facet resurfacing implant, as opposed to a cervical facet replacement implant which is used to replace an articular facet after its resection. The lumbar facet replacement disclosed in Martin is an example of a facet replacement implant. Unlike the implant of the Grob application, the implant disclosed in Martin is not designed for placement on an articular facet. Rather, the implant described in Martin replaces the articular facet after the articular facet is resected. Accordingly, the implant described in Martin could not be placed on any articular facet, especially not on a cervical articular facet, without causing severe harm, such as paralysis, to the patient.

7. Artificial disc implants are very different than the cervical facet implant of the Grob application. An artificial disc implant, like the implant described in Gill, could not be placed on cervical articular facet without causing severe harm, such as paralysis or death, to the patient. The claims of the Grob application involve implants that are configured for placement on superior and inferior articular facets to provide new articulating surfaces for the articular facets. The implant described in Gill could not be used in such a manner.

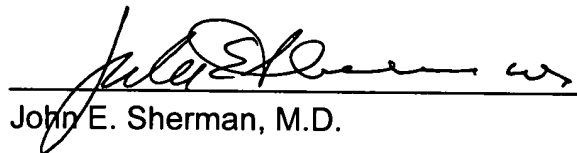
The lumbar facet implant described in Fitz is also very different than the cervical facet implant of the Grob application. Cervical vertebrae and lumbar vertebrae have different structures. Importantly, there is much less range of motion and spacing between articular facets of cervical vertebrae than there is between articular facets of

Docket No. HORA.P0102US
Serial No. 10/762,008

lumbar vertebrae. A particular implant may be suitable for use with lumbar articular facets and not suitable for use with cervical articular facets. The implant described in Fitz is such an implant. The Fitz implant is cone-shaped and designed to partially encase portions of the articular facets of lumbar vertebrae. Because of its shape, the Fitz implant is not suitable for use with cervical articular facets. Attempting to place the Fitz implant on cervical articular facets would likely result in causing severe damage to the patient.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/7/06



John E. Sherman, M.D.



JOHN EMERY SHERMAN, M.D.

EDUCATION

1974-1978

St. Olaf College
Northfield, Minnesota
Major: Chemistry

B.A. Magna Cum Laude

1978-1982

Washington University School of Medicine
St. Louis, Missouri

M.D.

RESIDENCY

1982-1983

University of Minnesota Department of General Surgery

1983-1987

University of Minnesota Department of Orthopedic Surgery

FELLOWSHIP

1989-1990

UCLA, Department of Orthopedics
Assistant Professor of Surgery-Spine

ACADEMIC APPOINTMENTS

1988-1990

Assistant Professor
UCLA, Department of Orthopedics

1995-Present

Assistant Clinical Instructor
University of Minnesota, Department of Orthopedics

BOARDS & CERTIFICATIONS

- 1989
American Board of Orthopaedic Surgery
- 1998
American Board of Orthopaedic Surgery
Recertification Examination
- 1998
American Board of Spinal Surgery
- 2004
American Board of Spinal Surgery Recertification

PRACTICE

- 1987-1989
Park-Nicollet Medical Center
General Orthopedics with concentration in spine surgery
- 1990-1997
Orthopedic Surgeons, Ltd.
Practice of Spine Surgery
- 1998-1999
John E. Sherman, M.D., P.A.
Practice of Spine Surgery
- 2000-2002
Institute for Low Back and Neck Care
- 2002-Present
Twin City Orthopedics-Orthopaedic Consultants Division

LICENSE

- 1983-Present
Minnesota 028212
- 1989-Present
California G066717

ORGANIZATION MEMBERSHIPS

American Academy of Orthopedic Surgeons
American Medical Association
Hennepin County Medical Society
Minnesota Medical Association
Minnesota Orthopedic Society

ORGANIZATION MEMBERSHIPS (cont.)

North American Spine Society
Spine Arthroplasty Society
Twin City Orthopedic Society
Swiss Spine Institute

HOSPITAL STAFF APPOINTMENTS

Fairview Southdale Hospital
Methodist Hospital
Abbott Northwestern Hospital
Veterans Administration Hospital, Minneapolis, Minnesota
Queen of Peace Hospital, New Prague, Minnesota

MEDICAL DIRECTORSHIPS/ADVISOR

1997-Present
Consultant, Zimmer Spine, Minneapolis, Minnesota
Disc Dynamics, Minneapolis, Minnesota
Anulex, Minneapolis, Minnesota
Spineology, Minneapolis, Minnesota
Consultant, Endius, Plainsville, Massachusetts

EDITOR

Spine-health.com

AWARDS

- 1988 President, Twin Cities Orthopedic Society
- 1991 Volvo Award, presented by International Society and Study of Lumbar Spine for Cauda Equina Compression: Neurological Recovery Following Immediate, Early, or Late Decompression
- 1991 Acromed Award, presented by North American Spine Society
- 1992 Young Investigator Award, presented by Orthopedic Research Society
- 1993 Acromed Award, presented by North American Spine Society Research Award, Spinal Cord Injury: The Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression

BOOK CHAPTERS

Lewandowski (coordinating editor): Innovations in Spinal Reconstruction
–Clinical Examples of Basic Science, Biomechanics, & Engineering

October 25, 2005

Draft Version 1.0

Chapter ## Improving the Outcome of Discectomy
 with Specific Attention to the Anulus Fibrosus

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Text Pages: 20 (31, inclusive of references)

Figures: 13

Tables: 0

References: 125

PAPERS

Spondylosis in Scheuermann's Disease
Spine 13: 251-255, 1987

Spinal Stenosis Secondary to Calcium Pyrophosphate Deposition (Pseudogout)
Clinical Orthopedics & Related Research
289: 127-130, 1993

Spinal Cord Monitoring: Results of Scoliosis Research Society and European Spinal Deformity Society Survey
Spine 16S: 54-61, 1991

Cauda Equina Compression: Neurologic Recovery Following Immediate, Early or Late Decompression
Spine 16: 1022-1028, 1991

Spinal Cord Injury: The Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression
Journal of Bone & Joint Surgery-American Volume 77(7):1042-9, 1995 Jul

Somatosensory Evoked Potential Spinal Cord Monitoring Reduces Neurologic Deficits After Scoliosis Surgery: Results of a Large Multicenter Survey
Submitted 1995 Electroencephalography and Clinical Neurophysiology
96: 6-11, 1995

Spinal Cord Monitoring with Cortical SEPs
Electroencephalography and Clinical Neurophysiology
Vol 97, No 4: S31-S32

Four-Year Follow-up Results of Lumbar Spine Arthrodesis Using the Bagby and Kuslich Lumbar Fusion Cage
Spine 25: 2656-2662, 2000

PRESENTATIONS

Scoliosis Research Society 9/86

Minnesota Orthopedic Society
Spondylolysis in Scheuermann's Disease 5/87

Orthopedic for Primary Care
Management of Common Ankle Injuries 10/88

Scoliosis Research Society 9/90
Spinal Cord Monitoring: Results of Scoliosis Research Society and European Spinal Deformity Society Survey

- American Academy of Orthopedic Surgery 2/91
Spinal Cord Monitoring: Results of Scoliosis Research Society and European Spinal Deformity Society Survey
- International Society for Study Lumbar Spine 5/91
Cauda Equina Compression: Neurologic Recovery Following Immediate, Early, or Late Decompression
- North American Spine Society 7/91
Cauda Equina Compression: Neurologic Recovery Following Immediate, Early, or Late Decompression
- Scoliosis Research Society 9/91
Cauda Equina Compression: Neurologic Recovery Following Immediate, Early, or Late Decompression
- Western Orthopedic Society 10/91
Cauda Equina Compression: Neurologic Recovery Following Immediate, Early, or Late Decompression
- American Academy of Orthopedic Surgery 2/92
Cauda Equina Compression: Neurologic Recovery Following Immediate, Early, or Late Decompression
- Orthopedic Research Society 2/92
Cauda Equina Compression: Neurologic Recovery Following Immediate, Early, or Late Decompression
- International Society for Study Lumbar Spine 6/93
Spinal Cord Injury: The Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression
- Western Orthopedic Society 8/93
Spinal Cord Injury: The Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression
- North American Spine Society 10/93
Spinal Cord Injury: The Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression
- Federation of Spinal Societies 2/91
Spinal Cord Monitoring: Results of Scoliosis Research Society and European Spinal Deformity Society Survey

PRESENTATIONS (cont.)

Ecole de Chirurgie de l'Assistance Publique de Paris	Paris, France	1/95
Biomechanical Rationale and Surgical Technique for the BAK Interbody Fusion System.		
U.S. Clinical Results using the BAK Interbody Fusion System. Pre-operative Evaluation and Templating Technique for the BAK Interbody Fusion System.		
CIOD Congress		2/95
U.S. Clinical Results using the BAK Interbody Fusion System 1995		
FOSA		2/95
Cervical Spine Research Society & American Spinal Cord Injury Society Spinal Cord Injury: Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression		
Society Combined Meeting Australian Spine Society & Neurosurgical Society		9/95
Spinal Cord Injury: The Pathophysiology of Spinal Cord Damage and Subsequent Recovery Following Immediate or Delayed Decompression		
Visiting Professor University of Malaysia: Kuala Lumpur		9/95
First International R. Roy-Camille Meeting on Spine.	Paris, France	1/96
Acute Surgical Complications in an Adult Spinal Stenosis Patient		
Lumbar Interbody Fusion Procedures of the Spine.	Plano, Texas	7/96
American Academy of Orthopedic Surgery	St. Louis, Missouri	4/97
Minimally Invasive Spinal Surgery Symposium		
Laparoscopic Lumbar Arthrodesis		
Lumbar Arthrodesis Utilizing Intradiscal Fusion Cages		
International Society for the Study of the Lumbar Spine	Singapore	6/97
Wrong Level Spine Surgery: An Analysis of Causes		
Clinical Update: Lumbar Interbody Fusion 1997 & Beyond	Seattle, WA	11/97
Lumbar Interbody Fusion in the Treatment of Spondylolisthesis		
American Academy of Orthopedic Surgery	St. Louis, Missouri	7/98
Least Invasive Spine Surgery, Complications of Fusion Cages		
North American Spine Society	San Francisco, CA	10/98
Interbody Fusion with BAK in Spondylolisthesis, Poster Presentation		
Clinical Update: Lumbar Interbody Fusion 1998 & Related Topics	Seattle, WA	11/98
Spondylolisthesis: Degenerative & Isthemic; Indications & Techniques		

PRESENTATIONS (cont.)

Complications of Spinal Fusion of the Lumbosacral Spine Anterior Lumbar Interbody Fusion: Indications & Technique	Olympic Valley, CA	3/99
American Academy of Orthopedic Surgery Least Invasive Spine Surgery, Fusion Baskets	St. Louis, Missouri	4/99
American Academy of Orthopedic Surgery Least Invasive Spine Surgery, Complications of Fusion Baskets	St. Louis, Missouri	4/99
North American Spine Society Indications of Spinal Fusion	Chicago, IL	10/99
North American Spine Society Four-Year Follow-up Results of Lumbar Spine Arthrodesis Using the BAK Lumbar Fusion Cage	Chicago, IL	10/99
Emerging Spinal Technologies-Center of Excellence Advanced Surgical Training in Interbody Techniques	Los Angeles, CA	6/00 3/01 5/01 10/01 2/02
Minimally Invasive Course Stand Alone Fusion Cages: Long Term Outcomes Complications of Fusion Cages	St. Louis, MO	7/00
Japan Society for the Study of Surgical Technique for Spine and Spinal Nerve Lateral Approach for Lumbar Spine With BAK Cage	Japan	9/00
6 th SSIS-Spine Surgeons International Symposium-Degenerative Spinal Disease: Selecting Surgical Techniques Stand Alone Interbody Cages: Does This Really Work	Napa, CA	9/00
Osteoporosis and Vertebral Body Compression Fractures: Medical Management and a New Minimally Invasive Surgical Procedure	Minneapolis, MN	5/01
Japan Society for the Study of Surgical Technique for the Spine and Spinal Nerve Polar Technique for the Treatment of Lumbar Degenerative Disease	Japan	9/01
"Progress in Spinal Fixation", International Symposium with Live Surgery, Berne, Switzerland, June 21-22, 2002 Overview of Cage Controversies		
The 9 th Annual Meeting of Japan Society for the Study of Surgical Technique for Spine and Spinal Nerves on September 14 th and 15 th , 2002 Cervical Interbody Fusion Cages a Minimum 4-Year Prospective Follow-up		

PRESENTATIONS (cont.)

American Academy of Orthopedic Surgery New Orleans, Louisiana Lumbar Interbody Fusion with the Threaded Cage: Six-Year Follow up	02/03
Spine Arthroplasty Society Phoenix, Arizona Argument for Nucleus Replacement	05/03
Spine Arthroplasty Society Phoenix, Arizona Biomechanical Results of Dynesys	05/03
North American Spine Society Annular Repair and Nucleoplasty	10/03
Spine Arthroplasty Society Vienna, Austria Dynesys Meeting - Chairman	05/04
Nonfusion Techniques in Spinal Surgery Vienna, Austria International Symposium – Basic Science and Early Results with Nucleoplasty	09/04
Chinese Speaking Orthopaedic Society Beijing, China – Dynamic Stabilization with Dynesys without Fusion for Degenerative Spinal Instability – PLIF versus/and TLIF procedures	09/04
Second Transatlantic Spine Congress Basel, Switzerland Innovations in Spine Surgery “Dynesys Early versus IDE Results”	11/04
North American Spine Society Early clinical experience with an in situ curable nucleus replacement implant one year follow up of a prospective nonrandomized multicenter clinical study Halm Henry, MD ^{1*} , Jean Charles L Huec, MD ² , Michael Ahrens, MD ¹ , Ulf Liljenqvist, MD ³ , John Sherman, MD ⁴ , Christopher Yeung, MD ⁵ , Hansen Yuan, MD ⁶ ¹ Neustadt i.H., Germany; ² Bordeaux, Bor, France; ³ Münster, Germany; ⁴ Edina, MN; ⁵ Phoenix, AR; ⁶ Syracuse, NY	09/05

JOHN EMERY SHERMAN, M.D.

Page 10

PRESENTATIONS (cont.)

Emerging Technologies

11/05

Spinal Panel – Piper Jaffrey

RESEARCH

Interbody Fusion Techniques, Motion Preservation Technology

INTERESTS

Family (Wife – Jane; Children – Ian, Scott, Brian, and Emma)

Classical Music, Golf, Triathlons